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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,287	11/23/2001	George Jackowski	2132.108	5379

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,287	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 are drawn to a biopolymer consisting of SEQ ID NO: 1, SEQ ID NO:2, or SEQ ID NO:3, classified in class 530, subclass 300 or class 530, subclass 350 for example.

II. Claims 3-9 are drawn to mass spectrometric analyses to identify or detect SEQ ID NO: 1, SEQ ID NO:2, or SEQ ID:3 in a patient sample, classified in class 435, subclass 7.1 for example.

III. Claims 29-32 are drawn to antibodies that bind SEQ ID NO: 1, SEQ ID NO:2, or SEQ ID NO:3, classified in class 530, subclass 387.1/387.2 and class 424, subclass 130.1 for example.

IV. Claims 10-28 and 33-38 are drawn to kits/methods which not only detect SEQ ID NO: 1, SEQ ID NO:2, or SEQ ID NO:3 but further requiring a correlation to disease state, diagnosing, therapeutic avenues, an/or risk assessment, classified in class 436, subclass 518 and class 424, subclass 93.1 for example.

2. The inventions are distinct, each from the other because of the following reasons:

A. Inventions **I and III** are drawn to two disclosed patentably distinct inventions (compositions comprising materially different limitations). Group I is directed to a biopolymer while Group IV is directed to antibodies with specificity for the biopolymer. The two products are independent and require different searches.

These separate products/compositions bear distinct structural or biochemical properties **Therefore, each disclosed patentably distinct composition is considered a separate invention.** In other words, the biopolymer (polypeptides) and antibodies are patentably distinct in terms of structure and function.

B. The methods of inventions of Group **II** and Group **IV** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventive methods are patentably distinct. Group II *merely detects* SEQ ID NO: 1, SEQ ID NO: 2, or SEQ ID NO:3; while Group IV is drawn to kits/methods that *detect/include* SEQ ID NO: 1, 2 or 3 and further correlates the detection to disease state assessment, product regulation, and therapeutic evaluations. The addition of the biopolymers or the additional correlation is not required in the method of invention II. Therefore the methods utilize different reagents and have different method steps (different modes of operation/function/effects).

C. Inventions **(I and III)** and **(II and IV)** are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the products (I and III) are materially different and can be used in any of the materially different processes/methods of invention II or Group IV.

It is recognized that although the search for the inventions may overlap they are not totally co-extensive, where the search for one would fully encompass the search for the others. Because these inventions are distinct for the reasons given above and the search required for Inventions I-IV are not mutually inclusive (i.e. the search for one invention is not required for the other inventions) restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups:

In addition, each detailed Group above reads on patentably distinct sequences (SEQ ID NO:1, 2, or 3). Each sequence is patentably distinct because they are unrelated sequences, therefore restriction is deemed proper and applied to each Group. For an elected Group drawn to an amino acid sequence (Group I, II, II, IV, or V), the Applicant must further elect a single amino acid sequence for consideration. For an elected Group drawn to nucleotide sequences, the Applicant must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making previous waiver for up to 10 elected nucleic acid sequences effectively impossible to implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C.121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a species election requirement.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Please note that the classifications in the restriction are illustrative only and **do not** represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes foreign patents and applications as well as literature searches.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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9/30/04

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
10/01/04